manufactured using a reactant having a specific chemical identity claimed as confidential by its supplier, the manufacturer must submit a notice directly to EPA containing all the information known by the manufacturer about the chemical identity of the reported substance and its proprietary reactant. In addition, the manufacturer must ensure that the supplier of the confidential reactant submit a letter of support directly to EPA providing the specific chemical identity of the confidential reactant, including the CAS number, if available, and the appropriate PMN or exemption number, if applicable. The letter of support must reference the manufacturer's name and PMN User Fee Identification Number under §700.45(c)(3) of this chapter. The statutory review period will commence upon receipt of both the notice and the letter of support.

* * * * *

e. Section 720.80 is amended by revising paragraph (b)(2) to read as follows:

§720.80 General provisions.

* * * * *

(b) * * *

(2) If any information is claimed as confidential, the person must submit, in addition to the copies specified by §720.40, a sanitized copy of the notice form (or electronic submission) and any attachments.

(i) The original and two copies of the notice, specified at §720.40 (or electronic submission) and attachments must be complete. The submitter must designate that information which is claimed as confidential in the manner prescribed on the notice form (or in EPA's electronic submission instructions).

(ii) The sanitized copy must be complete except that all information claimed as confidential in the original must be deleted. EPA will place this sanitized copy in the public file.

(iii) If the person does not provide the sanitized copy, or information in a health and safety study (except information claimed as confidential in accordance with §720.90), the submission will be deemed incomplete and the notice review period will not begin until EPA receives the sanitized copy or the health and safety study information is included, in accordance with §720.65(c)(1)(vii).

* * * * *

f. Section 720.95 is amended by revising the third sentence to read as follows:

§720.95 Public file.

* * * Any of the nonconfidential material described in this subpart will be available for public inspection in the TSCA Nonconfidential Information Center, Room B607, Northeast Mall, 401 M St., SW., Washington, DC between the hours of 1 p.m. and 4 p.m., weekdays, excluding legal holidays.

g. Section 720.102 is amended by revising paragraphs (c) and (d) to read as follows:

§720.102 Notice of commencement of manufacture or import.

* * * * *

(c) *Information to be reported on form.* (1) The notice must be submitted on EPA (Form 7710–56), which is available from the Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. The form must be signed and dated by an authorized official. All information specified on the form must be provided. The notice must contain the following information:

(i) The specific chemical identity of the PMN substance.

(ii) A generic chemical name (if the chemical identity is claimed as confidential by the submitter).

(iii) The premanufacture notice (PMN) number assigned by EPA.

(iv) The date of commencement for the submitter's manufacture or import for a non-exempt commercial purpose (indicating whether the substance was initially manufactured in the United States or imported). The date of commencement is the date of completion of non-exempt manufacture of the first amount (batch, drum, etc.) of new chemical substance identified in the submitter's PMN. For importers, the date of commencement is the date the new chemical substance clears United States customs.

(v) The name and address of the submitter.

(vi) The name of the authorized official.

(vii) The name and telephone number of a technical contact in the United States.

(viii) The address of the site where commencement of manufacture occurred.

(ix) Clear indications of whether the chemical identity, submitter identity, and/or other information are claimed as confidential by the submitter.

(2) If the submitter claims the chemical identity confidential, and wants the identity to be listed on the confidential portion of the Inventory, the claim must be reasserted and substantiated in accordance with §720.85(b). Otherwise, EPA will list the specific chemical identity on the public Inventory. Submitters who did not claim the chemical identity, submitter identity, or other information to be confidential in the PMN cannot claim this information as confidential in the notice of commencement.

(d) *Where to submit.* Notices of commencement of manufacture or import should be submitted to:

TSCA Document Control Office (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

* * * * *

Appendix A [Removed]

h. Appendix A to part 720 is removed.

3. In part 721:

PART 721—[AMENDED]

a. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2652(c).

b. Section 721.25 is amended by revising the last sentence of paragraph (a) to read as follows:

§721.25 Notice requirements and procedures.

(a)* * * The notice must be submitted on EPA Form 7710–25, and must comply with the requirements of part 720 of this chapter, except to the extent that they are inconsistent with this part 721.

* * * * *

[FR Doc. 95–7709 Filed 3–24–95; 3:32 pm]
BILLING CODE 6560–50–F

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40 CFR Part 721

[OPPTS–50595B; FRL–4921–9]

RIN 2070–AC14

Amendment for Expedited Process To Issue Significant New Use Rules for Selected New Chemical Substances; Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating an amendment to the regulations governing significant new uses of chemical substances. The amendment authorizes EPA to impose any of the ''significant new use'' designations in 40 CFR part 721 subpart B using expedited rulemaking procedures to promulgate ''significant new use'' rules (SNURs) for

certain new chemical substances not subject to the Toxic Substances Control Act (TSCA) section 5(e) Orders (referred to as ''non-5(e) SNURs''). Currently, the significant new use regulations limit the type of activities which EPA can designate as a significant new use by expedited rulemaking without first issuing a section 5(e) Order. This amendment allows EPA to promulgate expedited SNURs for certain new chemical substances without issuing a section 5(e) Order for the substance, and thereby facilitates EPA's ability to efficiently and expeditiously regulate new chemical substances.

DATES: This rule will become effective on May 30, 1995. In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern time on April 12, 1995.

FOR FURTHER INFORMATION CONTACT: James B. Willis, Acting Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554–1404, TDD: (202) 554–0551.

SUPPLEMENTARY INFORMATION: Under section 5 of TSCA, when EPA regulates activities associated with a new chemical substance described in a premanufacture notice (PMN), EPA generally issues an Order under section 5(e) of TSCA regulating the PMN submitter and/or promulgates a SNUR under section 5(a)(2) regulating all manufacturers and processors of the PMN substance. EPA promulgated a procedural ''Generic SNUR'' (or ''Expedited Follow-Up Rule'') in 40 CFR part 721 on July 27, 1989 (54 FR 31298). On February 8, 1993, EPA proposed amending the SNUR regulations in 40 CFR 721.170(c)(1) to authorize EPA to impose any of the ''significant new use'' designations in 40 CFR part 721 subpart B using expedited rulemaking procedures to promulgate non-5(e) SNURs. 58 FR 7676. (Public hearings were held in April 1993.) Previously, significant new use designations available for expedited non-5(e) SNURs were limited to environmental release activities and certain industrial, commercial, or consumer activities. This amendment authorizes EPA to include other important designations, such as protection in the workplace and hazard communication, in non-5(e) SNURs promulgated via expedited rulemaking procedures.

As explained in the rule proposal: ''Whereas a section 5(e) Order applies only to the original PMN submitter who signs the Order, a SNUR applies to all manufacturers and processors of the chemical substance. The reporting requirements of a non-5(e) SNUR apply also to the original PMN submitter (because, without a section 5(e) Order, the PMN submitter is not exempted by 40 CFR 721.45(i)). Since only one Agency action is required instead of two, and fewer EPA resources are necessary to obtain similar regulatory results, a non-5(e) SNUR is more efficient than a combination of section 5(e) Order and '5(e)-SNUR' (under 40 CFR 721.160) to regulate new chemical substances.'' 58 FR 7677. The rule proposal also stated that promulgation of a non-5(e) SNUR would allow the PMN submitter to commence commercial manufacture of the PMN substance sooner than would issuance of a section 5(e) Order followed by promulgation of a 5(e)-SNUR.

I. Authority

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' EPA must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). The enumerated factors pertain to the potential for increased manufacturing and processing volume, increased exposure, and changes in anticipated methods of manufacture, processing, distribution and disposal. Once EPA has, by rule, determined that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before commencing any manufacturing, importing, or processing activities designated by the SNUR as a ''significant new use.'' The mechanism for reporting under this requirement is set out in 40 CFR 721.10.

The supporting rationale and background for SNURs are more fully set out in the preamble to EPA's first SNURs issued under the Expedited Follow-Up Rule and published on April 24, 1990 at 55 FR 17376. Consult that preamble for further information on the objectives, rationale, and procedures for the rules and on the basis for significant new use designations.

II. Applicability of General Provisions

General provisions for SNURs appear in subpart A of 40 CFR part 721. These provisions describe persons subject to SNURs, recordkeeping requirements, exemptions to reporting requirements, and applicability of SNURs to uses occurring before the effective date of a SNUR. Rules on user fees appear in 40 CFR part 700. Persons subject to a SNUR must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under section 5(a)(1)(A) of TSCA. In particular, these requirements include the information submission requirements of section 5(d)(1) and 5(b), the exemptions authorized by section 5(h)(1), (2), (3), and (5), and the regulations at 40 CFR part 720. Once EPA receives a SNUR notice, EPA may take regulatory action, if appropriate, under sections 5(e), 5(f), 6, or 7 to control the activities on which it has received the SNUR notice. If EPA does not take action, EPA is required under section 5(g) to explain in the **Federal Register** its reasons for not taking action.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret section 12(b) appear at 40 CFR part 707.

III. Discussion of Comments and Final Rule

The public comments submitted to EPA on the proposed rule indicated a need for clarification regarding EPA's goals underlying this rule amendment. The goals that EPA believes are promoted by this amendment are: (1) to regulate new chemical substance risks using fewer EPA resources, and (2) to allow PMN submitters proposing to produce such substances to commence commercial manufacture sooner (subject to appropriate limitations that reduce risk). The amendment will achieve these goals by eliminating language in 40 CFR §721.170(c)(1) that previously prevented EPA from promulgating expedited non-5(e) SNURs containing worker protection or hazard communication requirements. In cases where those types of requirements are appropriate, this amendment will enable EPA and the PMN submitter to bypass development of a section 5(e) Order and proceed directly to promulgation of a SNUR. The PMN submitter and other interested parties will generally have a similar opportunity for dialogue with EPA and input into development of the specific regulatory terms as they do in the development of a section 5(e) Order/5(e)-SNUR combination.

1. *Comment.* Many comments indicated concern that EPA would use the amendment to promulgate more SNURs with less input from the PMN submitter.

EPA Response. To the contrary, EPA's intentions are to: (1) issue fewer section 5(e) Orders, not more SNURs; and (2) where appropriate, develop non-5(e) SNURs based on voluntary amendments of PMNs that accomplish the same end as section 5(e) Order/5(e)-SNUR combinations but without the extra step.

In particular, EPA intends a process involving the active participation of the original PMN submitter for the substance that may be subject to a SNUR; this process will be less formal than negotiating a section 5(e) Consent Order.

As explained in the preamble to the proposed rule (58 FR 7678, February 8, 1993), the non-5(e) SNUR process provides interested persons several opportunities for comment. Section 721.170(d)(2) requires EPA to notify the PMN submitter at least 7 days before expiration of the 90–day PMN review period regarding the Agency's risk concerns and the activities under consideration for designation as a significant new use. In most cases, EPA actually expects to provide this notice many days before the ''Day-83'' deadline required by section 721.170(d)(2). Of course, once a PMN submitter receives this notice, the submitter may respond to EPA with comments regarding both the risk concerns and the potential regulatory terms or ''significant new use'' designations. Furthermore, the expedited ''direct final'' non-5(e) SNUR rulemaking procedure does provide a comment opportunity, which was described in the preamble to the proposed rule (58 FR 7678) as well as in the preamble to the Generic SNUR (54 FR 31305, July 27, 1989). Thus, this expanded non-5(e) SNUR process will in fact provide individual notice to the PMN submitter before the non-5(e) SNUR is published, followed by notice and opportunity for comment to all persons when the non-5(e) SNUR is published in the **Federal Register**.

Also as stated in the rule proposal: ''A non-5(e) SNUR is typically appropriate for PMNs on chemical substances expected to be toxic but where the PMN indicates the submitter's intention to limit activities, implement control measures, or otherwise adequately mitigate human exposures and environmental releases. Activities described in such PMNs may not present an unreasonable risk of injury to human health or the environment so as to warrant the issuance of an Order under section 5(e) of TSCA [followed by promulgation of a 5(e)–SNUR], but deviations from the described activities may present an unreasonable risk warranting the imposition of regulatory controls via a section 5(e) Order. In those cases, a non-5(e) SNUR may be the least burdensome regulatory alternative for the Agency to pursue, as it will allow the PMN submitter to proceed with planned activities while requiring notification to, and review by, EPA for activities which have not been reviewed.'' 58 FR 7677.

Additionally, using this non-5(e) SNUR process, where EPA perceives that use of a new chemical substance as described in the PMN may present unreasonable risk, then, instead of suggesting a section 5(e) Consent Order/5(e)-SNUR combination, EPA may informally request the submitter to amend its PMN to include appropriate exposure controls. If the submitter agrees to amend its PMN accordingly, EPA can then allow the submitter to commence manufacture immediately upon expiration of the 90–day PMN review period. Because the amended PMN would reflect the same controls that will be in the non-5(e) SNUR, EPA will not require the submitter to wait until the non-5(e) SNUR is published to commence commercial manufacture.

If, instead, the PMN submitter cannot reach agreement with EPA regarding the need or appropriateness of the modified terms for the PMN, and/or prefers to negotiate a formal section 5(e) Consent Order, EPA may then issue a section 5(e) Order. However, experience shows that additional time and resources will very probably need to be expended before the section 5(e) Order can be finalized, which must occur before EPA will allow the PMN review period to expire, which in turn must precede commencement of commercial manufacture of the PMN substance. Section 5(e)(1)(B)(ii) of TSCA prohibits EPA from issuing a section 5(e) Order after expiration of the 90–day statutory review period. Therefore, EPA will not allow the review period to expire until the section 5(e) Order is finalized, and ''extension'' (pursuant to TSCA section 5(c)) or ''suspension'' (pursuant to 40 CFR 720.75(b)) of the review period is usually necessary to allow sufficient time for development of the section 5(e) Order. TSCA section 5(a) prohibits commencement of commercial manufacture of the PMN substance before the 90–day statutory PMN review period expires. Furthermore, if EPA and the submitter cannot agree on the terms for a section 5(e) Consent Order, EPA can issue a section 5(e) Order unilaterally.

Thus, this rule amendment is intended to eliminate unnecessary section 5(e) Orders and should not itself increase the number of new chemical substances regulated by EPA via SNURs under section 5 of TSCA. Rather, substances that would formerly have been regulated by 5(e)-SNURs may now be regulated by non-5(e) SNURs. The amendment still requires EPA to provide notice allowing the PMN submitter (or others) to respond to EPA with comments regarding the perceived risks and the proposed regulatory requirements for a given new chemical substance.

2. *Comment.* Some comments indicated a desire for criteria to restrict EPA's discretion as to when it would use the non-5(e) SNUR procedure. The Chemical Manufacturers' Association (CMA) suggested that EPA should commit to promulgating expedited non-5(e) SNURs only when EPA finds that the chemical substance ''may present an unreasonable risk,'' i.e., the standard articulated in TSCA section 5(e) for the issuance of administrative orders.

EPA Response. EPA has stated many times that TSCA authorizes EPA to promulgate a SNUR without finding that a chemical substance ''may present unreasonable risk.'' Rather, section 5(a)(2) of TSCA and 40 CFR 721.170(b), which is not being amended in this rulemaking, set forth the criteria EPA has used and will continue to use for non-5(e) SNURs.

As discussed above, where EPA perceives that the scenario described in a PMN may present an unreasonable risk, EPA may request the submitter to amend the PMN to include appropriate exposure controls. If the submitter refuses, EPA would not promulgate a non-5(e) SNUR, but would likely attempt to negotiate a section 5(e) Consent Order. Unlike promulgation of a non-5(e) SNUR, to issue a section 5(e) Consent Order, EPA must determine that activities associated with the PMN substance ''may present an unreasonable risk'' of injury to human health or the environment. Again, however, extension or suspension of the review period would be necessary to allow sufficient time for development of the section 5(e) Order, and, if EPA and the submitter cannot agree on the need or terms for a section 5(e) Consent Order, EPA can issue a section 5(e) Order unilaterally.

Nevertheless, as elaborated elsewhere, EPA believes that non-5(e) SNURs will save time and resources for both EPA and industry without unduly sacrificing the ability to negotiate the regulatory terms. EPA expects that PMN submitters will recognize this and will generally prefer a non-5(e) SNUR over a section 5(e) Order/5(e)–SNUR combination.

3. *Comment.* Many commenters disapproved of EPA's ability to use the expedited non-5(e) SNUR procedure to impose regulatory requirements not listed in subpart B of 40 CFR part 721.

EPA Response. The final rule limits ''significant new use'' designations for non-5(e) SNURs to subpart B provisions only. EPA expects that limiting expedited non-5(e) SNURs to the standard ''significant new use'' designations published in subpart B of

40 CFR part 721 will help provide PMN submitters with a clear understanding when notified by EPA of the regulatory terms that EPA intends to apply to their PMN substance via a non-5(e) SNUR.

If, in the future, EPA decides that additional ''significant new use'' designations are needed for non-5(e) SNURs, EPA can add those designations to subpart B via notice and comment rulemaking or promulgate individual SNURs containing those designations through notice and comment rulemaking.

4. *Comment.* Several commenters disagreed with EPA's assertion that, since suspensions to issue section 5(e) Orders would be eliminated, the proposed amendment would allow commercial manufacture to commence sooner. They stated the amendment would actually cause greater delay because EPA could declare any use inconsistent with the PMN to be a significant new use. They claim that the PMN submitter will need more time to identify all potential uses and associated information before submitting a PMN, so that EPA will not promulgate a SNUR requiring further notices for those uses of the substance.

EPA Response. The comment indicates a need to clarify how EPA regulates new chemical substances and particularly how the word ''use'' is employed in the context of new chemical substance SNURs and section 5(e) Consent Orders. The SNURs promulgated by EPA to date for new chemical substances show that EPA rarely, if ever, designates as a ''significant new use'' every activity not expressly contemplated in the PMN. Rather, EPA generally defines a ''significant new use'' for new chemical substances as activities lacking specific exposure controls (such as gloves, goggles, respirators and waste disposal) which therefore may present an unreasonable health or environmental risk. EPA will define as ''significant'' any use not identified in the PMN only where the substance is expected to be toxic and EPA cannot be certain that specific exposure controls will adequately mitigate all concerns. In sum, the amendment is not intended to change the substantive content or terms that EPA has used to regulate new chemical substances or to write SNURs in the past; rather, it is a procedural change enabling EPA to establish those same terms in an expedited SNUR without first issuing a section 5(e) Consent Order. This amendment should not change the amount of time and effort a PMN submitter must invest to identify potential uses of the new chemical substance. PMN submitters will continue to be required to provide information that is known to or reasonably ascertainable by the submitter when the PMN is submitted and throughout the PMN review period. (15 U.S.C. 2604(d)(1)(A), 40 CFR 720.45).

5. *Comment.* One commenter stated that certain designations in subpart B are ''by their nature'' not appropriate for non-5(e) SNURs (quoting the preambles to the proposed and final Generic SNUR, see e.g., 54 FR 31304). The commenter also stated ''EPA should not designate the failure to use personal protective equipment as a significant new use of a chemical substance that has completed premanufacture review and is not subject to an Order under Section 5(e). If such protection is required, it should be imposed on the initial manufacturer who submitted the PMN pursuant to a Section 5(e) Consent Order .... EPA should not shortcut this process simply because 'a non-5(e) SNUR is more efficient than a combination of Section 5(e) order and a 5(e) SNUR ... to regulate new chemical substances.''' 58 FR 7677.

EPA Response. Several provisions in subpart B (i.e., 40 CFR 721.80(k), (q), and (t)) expressly refer to terms of the section 5(e) Consent Order and are thus inapplicable to non-5(e) SNURs. There is no need to specifically exclude these provisions from §721.170.

Based on over 4 years of experience with 5(e)–SNURs and non-5(e) SNURs under §§721.160 and 721.170, EPA now believes that provisions for worker protection and hazard communication should be available if EPA and the PMN submitter prefer to bypass the cumbersome section 5(e) Order/5(e)–SNUR process and go directly to a non-5(e) SNUR. Under the revised non-5(e) SNUR process, allowing designation of any of the ''significant new use'' provisions in subpart B, risks to workers can be controlled via SNURs without the need to also issue Consent Orders.

EPA believes the imposition of worker protection requirements in a non-5(e) SNUR is appropriate where the new chemical substance is expected to be toxic to humans and the PMN indicates that the submitter will implement worker protection measures. Again, this non-5(e) SNUR will not only save EPA resources, but will also allow the PMN submitter to commence manufacture sooner (i.e., immediately upon expiration of the 90–day review period, rather than suspending or extending the review period to negotiate a section 5(e) Order), provided that the submitter does in fact implement the stated protective measures so that the submitter is not required by the SNUR to submit another notice to EPA. The non-5(e) SNUR will bind the PMN submitter as effectively as a section 5(e) Order while saving the submitter the costs of delayed marketing of the new chemical substance.

6. *Comment.* EPA should not disrupt business by defining as a ''significant new use'' an activity which the original PMN submitter or another company commences between the filing of the notice of commencement (NOC) of manufacture (per 40 CFR 720.102) and the publication of the SNUR.

EPA Response. EPA generally does not consider those activities that commenced prior to publication of a proposed SNUR to be ''significant new uses.'' In SNUR preambles for individual chemicals, EPA routinely states that a ''new'' use is one that is not ongoing when the proposed SNUR is published in the **Federal Register**. If EPA is informed that a use which it proposes to define as ''new'' was already ongoing before the proposal was published, EPA will generally determine that use is not ''new.'' See, e.g., 57 FR 31326, July 15, 1992. (One exception would be if the original PMN submitter engaged in an activity prohibited by a section 5(e) Order.)

7. *Comment.* Employers have hazard communication and worker protection obligations under the Occupational Safety and Health Act without regard to the existence of TSCA section 5(e) Orders and SNURs. EPA should not over extend itself into the area of occupational safety and health.

EPA Response. TSCA section 5 authorizes EPA to review and regulate new chemical substances to prevent unreasonable risks to human health and the environment. A senate report discussion of TSCA section 5 expressly notes that the Federal statutes existing when TSCA was enacted, including specifically the Occupational Safety and Health Act, ''do not provide for this type of premarket scrutiny.'' *S. Rept. No. 698, 94th Cong. 2d Sess. 1 (1976).* Requirements imposed by the Occupational Safety and Health Administration (OSHA) may not always apply to new chemical substances governed by TSCA section 5. For example, OSHA hazard communication requirements only apply to a substance for which there is at least one positive study (29 CFR 1910.1200(d)(2)), whereas many new chemical substances have not been tested at all. Furthermore, OSHA permissible exposure limits (PELs) (29 CFR Part 1910) generally apply only to specific chemical substances, and very few new chemical substances subject to section 5 of TSCA are subject to OSHA PELs. Lastly, the requirements of EPA's worker protection and hazard

communication provisions in section 5(e) Consent Orders and SNURs are consistent with OSHA's requirements.

8. *Comment.* One commenter stated that the increased incidence of non-5(e) SNURs would subject more chemicals to TSCA section 12(b) export notification requirements, increasing the burden on industry and EPA to report such activity. The commenter suggested a mechanism so that substances subject to a SNUR but contained in finished products or a small percentage of a mixture were not subject to TSCA 12(b) notification.

EPA Response. As stated previously in response to other comments, the intent of this rule amendment is not to increase the number of new chemical substances regulated by EPA. Rather EPA expects to offer PMN submitters the option of a non-5(e) SNUR, instead of a section 5(e) Consent Order. In either instance, EPA has determined that exposure controls are needed and will regulate the substance through one of those procedural mechanisms. This rule will not increase the section 12(b) reporting burden on industry or EPA.

The same comment suggesting a *de minimis* exemption for section 12(b) reporting was recently submitted on a proposed amendment to the section 12(b) rule at 40 CFR part 707, subpart D. EPA considered this comment in that rulemaking and stated in the preamble to the final rule amending the section 12(b) rule: ''While de minimis–type regulatory exemptions may be appropriate in many circumstances, at the present time, EPA believes it is preferable to provide foreign countries 12(b) notifications so they have the opportunity to make their own determinations regarding what level of a chemical in mixtures is deemed important. However, if further experience with the 12(b) or PIC [Prior Informed Consent joint program of the United Nations Environment Programme and the Food and Agriculture Organization] programs indicate that a *de minimis* regulatory exemption is warranted, EPA will reexamine this option at a later time.'' 58 FR 40240–41; July 27, 1993. Therefore, under the current rules implementing section 12(b) of TSCA (40 CFR part 707, subpart D), if a substance or mixture is subject to a section 5(e) Order or rule, then export notification is required, except for substances contained in ''articles'' (as defined in 40 CFR 720.3(c)).

9. *Comment.* The original Generic SNUR, including the restriction on non-5(e) SNUR designations, was negotiated by a multi-interest dialogue group and should not be changed unilaterally by EPA.

EPA Response. EPA has followed the notice and comment rulemaking procedures required by the Administrative Procedure Act, and believes it has improved the final rule amendment in direct response to the valuable comments that were submitted. Given the elimination of non-subpart B provisions, the benefits to PMN submitters from this rulemaking, and the potential delays of procedural approaches other than promulgating this final rule at this time, EPA has decided that it is in the public interest to go forward with this final rule. EPA expects this final rule to satisfy all statutory requirements and most, if not all, interested parties.

IV. Economic Analysis

The Agency's complete economic analysis is available in the public record for this rulemaking (OPPTS–50595B). The regulatory impact analysis estimates the costs and benefits attributable to the final regulation. In this case, the analysis also contains estimates for three amendments to other regulations, namely the Revisions of Premanufacture Notification Regulations, the Revision of Exemption for Chemical Substances Manufactured in Quantities of 1,000 Kilograms or Less Per Year, and the Revisions of Exemption for Polymers. As these regulations are amendments to current regulations, the costs and benefits are incremental and estimate the effect of the amendment with respect to the old regulation.

This non-5(e) SNUR amendment will eliminate the need to develop a section 5(e) Consent Order before promulgating an expedited SNUR in those cases where EPA determines that activities described in the PMN submission will not present unreasonable risk. The major industry benefit is the avoidance of the delay and costs associated with negotiating a Consent Order; generally, the submitter will be able to commence commercial manufacture immediately after the 90–day PMN review period without suspending or extending it. The submitter, along with other manufacturers and processors, will be bound by the expedited SNUR.

Industry savings from this amendment are based on avoidance of delay costs and are estimated to range from $65,000 to $330,000 per year. Annual government savings are estimated to range from $240,000 to $960,000. These estimates are based on the following assumptions: (1) 1,000 to 3,000 PMNs will be submitted annually; (2) in the absence of this amendment, 5% of these PMNs will be subject to section 5(e) Orders; and (3) with this amendment, 40% of these section 5(e) Orders will be avoided and replaced by non-5(e) SNURs.

V. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPPTS–50595B). The record includes basic information and comments considered by the Agency in developing this rule. A public version of the record is available in the TSCA Nonconfidential Information Center, from 12 noon to 4 p.m., Monday through Friday, except legal holidays. The TSCA Nonconfidential Information Center is located in Rm. NE–B607, Northeast Mall, 401 M St., SW., Washington, DC.

VI. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51835, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the Order defines a ''significant regulatory action'' as an action that is likely to (1) have an annual effect on the economy of $100 million or more, or adversely and materially affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant'') (2) create serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to Executive Order 12866 (58 FR 51735, October 4, '993) it has been determined that this rule is not a ''significant regulatory action'' under section 3(f) of the Order. This action is therefore not subject to OMB review.

B. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Agency has determined that this regulatory action will not impose any adverse economic impacts on small entities. EPA believes that, even if all of the

SNUR notice submitters were small firms, the number of small businesses affected by this rule will not be substantial.

C. Paperwork Reduction Act

There is no additional reporting burden associated with this amendment. The information collection requirements in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3502 et seq., and have been assigned OMB control number 2070–0012.

List of Subjects in 40 CFR Part 721

Chemicals, Environmental protection, Hazardous materials, Recordkeeping and reporting requirements, Significant new uses.

Dated: March 21, 1995.

Carol M. Browner,

Administrator.

Therefore, 40 CFR Chapter I, part 721 is amended as follows:

PART 721 — [AMENDED]

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. By revising §721.170(c)(1) to read as follows:

§721.170 Notification requirements for selected new chemical substances that have completed premanufacture review.

* * * * *

(c) * * *

(1) When EPA decides to establish significant new use reporting requirements under this section, EPA may designate as a significant new use any one or more of the activities set forth in subpart B of this part. In addition, EPA may designate specific recordkeeping requirements described under subpart C of this part that are applicable to the substance.

* * * * *

[FR Doc. 95–7710 Filed 3–24–95; 3:32 pm]

BILLING CODE 6560–50–F

40 CFR Part 723

[OPPTS–50594B; FRL–4929–8]

RIN 2070–AC14

Premanufacture Notification Exemptions; Revisions of Exemptions for Polymers; Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating amendments to the polymer exemption rule to expand the exemption criteria and exempt manufacturers of eligible polymers from certain section 5 premanufacture notification (PMN) requirements. EPA has determined that the manufacture, processing, distribution in commerce, use, and disposal of new chemical substances meeting the revised polymer exemption criteria will not present an unreasonable risk of injury to human health or the environment under terms of the exemption. These final amendments reflect criteria developed and used by EPA to assess the hazards associated with new polymeric substances over the past 15 years the New Chemicals Program has been in place. EPA believes that these amendments will encourage the manufacture of safer polymers by reducing industry's reporting burden for this category of chemical substances.

DATES: This rule will become effective May 30, 1995. In accordance with 40 CFR 23.5 (50 FR 7271), this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern time on April 12, 1995.

FOR FURTHER INFORMATION CONTACT: James B. Willis, Acting Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554–1404; TDD: (202) 554–0551.

SUPPLEMENTARY INFORMATION: The polymer exemption rule was originally promulgated on November 21, 1984. The supporting rationale and background for that exemption was published at 49 FR 46066 on November 21, 1984 and 46 FR 54688 on November 3, 1981. On February 8, 1993, EPA proposed amendments to the 1984 polymer exemption rule (58 FR 7679). Consult those documents for further information on the objectives, rationale, and procedures for the rule and the basis for the finding that polymers eligible for exemption will not present an unreasonable risk of injury to human health and the environment under terms of the exemption. The docket control number for this document is OPPTS–50594B.

The amended rule allows manufacture and distribution of polymers meeting the exemption criteria without submission of a PMN or an exemption notice prior to commencement of manufacture for a commercial purpose under terms of the exemption. However, manufacturers of exempted polymers are required to submit an annual report on exempted polymers for which manufacture or importation commenced for the first time under terms of the exemption during the preceding calendar year. Recordkeeping requirements are retained as part of the rule to document compliance with the exemption criteria. Overall, these amendments constitute a substantial revision of the existing polymer exemption rule.

I. Background

A. Statutory Authority

Section 5(a)(1) of TSCA requires that persons notify EPA at least 90 days before they manufacture or import a new chemical substance for commercial purposes. A ''new chemical substance'' is any substance that is not on the Inventory of Chemical Substances compiled by EPA under section 8(b) of TSCA. Section 5(h)(4) of TSCA authorizes EPA, upon application and by rule, to exempt the manufacturer or importer of any new chemical substance from part or all of the provisions of section 5 if the Agency determines that the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance will not present an unreasonable risk of injury to human health or the environment. In this preamble and under the rule, references to ''manufacture'' and ''manufacturer'' include ''import'' and ''importer'', respectively, as defined in TSCA section 3 and the PMN rule.

B. History/Rationale

In 1984, the Agency published a TSCA section 5(h)(4) rule granting an exemption for persons who manufacture or import certain polymers, set forth at 40 CFR 723.250. Since promulgation of the 1984 polymer exemption rule (the ''1984 exemption''), the Agency has reviewed over 2,000 polymers submitted as polymer exemption notices in the 21–day review process in addition to over 10,000 polymers submitted as PMNs since the initiation of the 90–day PMN review process in 1979. In the course of performing hazard and risk assessments for these polymers, the Agency has developed internal guidelines for identifying polymeric substances that do not present an unreasonable risk of injury to human health or the environment. These guidelines are based on (1) EPA's ongoing review of the available literature on the toxicity of polymers, (2) EPA's analyses of various samples of the PMN polymer data base, (3) information provided to EPA by outside groups